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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/899,980	07/06/2001	Gillian A. Kingsbury	MPI99-131P1RNDV1AM	5076

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MILLENNIUM PHARMACEUTICALS, INC.
40 Landsdowne Street
CAMBRIDGE, MA 02139

EXAMINER

JUEDES, AMY E

ART UNIT PAPER NUMBER

1644

DATE MAILED: 05/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/899,980	Applicant(s) KINGSBURY ET AL.	
	Examiner Amy E. Juedes, Ph.D.	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 58-60,62 and 64-71 is/are pending in the application.
- 4a) Of the above claim(s) 67-71 is/are withdrawn from consideration.
- 5) ☐ Claim(s) 58,59 and 64 is/are allowed.
- 6) ☒ Claim(s) 58-60,62 and 64-66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/6/01</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Applicant's amendment and remarks, filed 1/13/06, are acknowledged.

Claims 60 and 62 have been amended.

Claims 67-71 have been added.

Claims 61 and 63 have been cancelled.

Claims 58-60, 62, and 64-71 are pending.

2. Newly submitted claim 67-71 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 67-71 are drawn to a method of identifying a compound which binds a polypeptide. Thus claims 58-60, 62, and 64-66 are related to claims 67-71 as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product, the isolated polypeptide, could be used to immunize an animal to generate specific antibodies.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 67-71 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

3. The objection to the title is withdrawn, in view of Applicant's amendment.

4. Applicant states that copies of references AF-DI have been submitted. However, all of the references were not found in the file. Therefore, only the references that were found in the file have been initialed, and the rest have been lined through. Additionally, references AA-AE have been lined through since they were previously considered.

5. The objection to the drawings is withdrawn, in view of Applicants submission of the corrected drawings on 3/6/06.

6. The rejection of claims 60 and 62 under 35 U.S.C. 112 second paragraph is withdrawn in view of Applicant's amendment. The

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cancellation of claims 61 and 63 renders the rejection moot.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 65-66 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

As set forth previously, The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically:

An isolated polypeptide further comprising a heterologous polypeptide or Ig polypeptide, where said isolated polypeptide is the polypeptide defined in claims 60, 62, or 64.

In the Preliminary Amendment, filed 7/6/01, Applicant indicates that support for the Claims 58-66 can be found on pg. 24, line 29 to page 26, line 16 and page 34, line 21 to page 36, line 21.

A review of the specification fails to reveal support for the new limitations.

At page 27, the specification discloses, that a fusion protein "comprises the polypeptide in SEQ ID NO: 13 or a fragment thereof which includes the carboxy-terminus of the polypeptide and a heterologous polypeptide." Note that the specification does not disclose a fusion protein comprising an isolated polypeptide comprising amino acid residues 125 to 158, 100-158, 75-158, 50-158, or 25-158 of SEQ ID NO: 13, as now claimed. Neither does the specification disclose an Ig polypeptide comprising amino acid residues 125 to 158, 100-158, 75-158, 50-158, or 25-158 of SEQ ID NO: 13.

Applicant's arguments, filed 1/13/06, have been fully considered but they are not persuasive.

Applicant argues that the specification discloses fusion polypeptides comprising the carboxy terminus of SEQ ID NO: 13, and that each of the polypeptides described in claims 60, 62, and 64 comprise amino acid residue 158 (i.e. the carboxy terminal residue). However, a fusion polypeptide comprising the carboxy terminus of SEQ ID NO: 13 is the disclosure of a broad genus of polypeptides, and does not provide adequate support for the specific species of fusion polypeptides comprising the

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specific amino acid residues recited in claims 60, 62, and 64. It is well established that the disclosure of a genus does not provide adequate description for a species within said genus.

8. It is noted that this application adds and claims additional disclosure not presented in the priority applications. Since this application names an inventor or inventors named in the prior application, it may constitute a continuation-in-part of the prior application. Should applicant desire to obtain the benefit of the filing date of the prior application, attention is directed to 35 U.S.C. 120 and 37 CFR 1.78.

A supplemental oath or declaration is required under 37 CFR 1.67. The new oath or declaration must properly identify the application of which it is to form a part, preferably by application number and filing date in the body of the oath or declaration. See MPEP §§ 602.01 and 602.02. The subsequently filed oath or declaration must refer to both the application and the amendment. See MPEP 608.04(b).

9. The following are new grounds of rejection.

10. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 58-60, 62, and 64-66 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by substantial asserted utility or a well established utility.

The claimed polypeptide (SEQ ID NO: 13) is not supported by a substantial utility because the specification states only that SEQ ID NO: 13 encodes a novel splice variant of the human 103 gene locus, which also encodes other known splice variants such as ST2. While Applicant has disclosed that SEQ ID NO: 13 appears to be expressed in Th2 cells, no function for the polypeptide is disclosed. The only functional data provided relates to the ST2 splice variant, which can decrease Th2 responses when administered as a fusion polypeptide. However, the ST2 polypeptide comprises 323 amino acids, while the instantly claimed SEQ ID NO: 13 comprises only 158 amino acids. It seems unlikely that SEQ ID NO: 13, which only represents less than half of the amino acids of the ST2 protein, would function in an identical manner to ST2. Thus, the disclosed use of the 103 gene

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products, including SEQ ID NO: 13, for modulating T cell responses, does not constitute a substantial utility, since all the data provided about the role of 103 gene products in modulating T cell responses was performed using the ST2 protein. Applicant has not provided any evidence of the function of SEQ ID NO: 13, nor demonstrated that SEQ ID NO: 13 can function in a similar manner to the splice variant ST2. In fact, the art teaches that the ST2 gene family including the splice variants ST2, ST2L, and ST2V, have distinct promoters and distinct assignments in physiological functions which may vary among cells and tissues (see Tago et al., pg. 1378 and 1380). Therefore, defining a "real world" context of use for SEQ ID NO: 13 would require carrying out further research. See *Brenner v Manson*, 383 U.S. 519, 535-36, 148 USPQ 689, 696 (1966), which states that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion." Note, because the claimed invention is not supported by a substantial asserted utility for the reasons set forth above, credibility has not been assessed. Neither the specification as filed nor any art of record discloses or suggests any property or activity of a SEQ ID NO:13 that another non-asserted utility would be well established for the polypeptide.

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 58-60, 62, and 64-66 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

13. Claims 60 and 62 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, there is insufficient written

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description to show that Applicant was in possession of isolated polypeptides encoded by a nucleic acid molecule which hybridizes to SEQ ID NO: 12 and comprising amino acid residues 150-158 of SEQ ID NO: 13.

It is noted that Applicant states in the remarks filed on 1/13/06 that claims 60 and 62 are intended to encompass polypeptides that may be variants of SEQ ID NO:13, but have the limitation that they comprise amino acid residues 150-158 of SEQ ID NO: 13. Thus, the claims encompass a genus of variants of SEQ ID NO: 13. Said genus might include any substitution, deletion, or addition to SEQ ID NO: 13. Furthermore, the claims might encompass other, as yet unidentified, splice variants or related proteins derived from other species. Therefore, the skilled artisan cannot envision all the contemplated species of polypeptides encompassed by the instant claims. In contrast to the broad genus of polypeptides encompassed by claims 60 and 62, Applicant has not disclosed a single species of "variant" that comprises amino acid residues 150-158 and is encoded by a nucleic acid that hybridizes to SEQ ID NO: 12. Therefore, one of skill in the art would conclude that the specification fails to adequately describe the claimed invention. See *Eli Lilly*, 119 F.3d 1559, 43 USPQ2d 1398.

14. No claim is allowed.

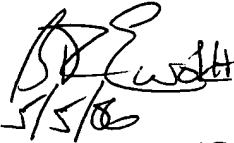
15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E. Juedes, Ph.D. whose telephone number is 571-272-4471. The examiner can normally be reached on 8am - 5pm, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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May 4, 2006


5/5/06
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